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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,043	12/04/2003	Kazuhisa Tanabe	163852020000	4854

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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/727,043

Applicant(s)

TANABE ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-8,12,14,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,12,14,16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

2. Claims 1, 3, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman (US Patent 6616613) in view of Utsugi (US Patent Application Publication 2001/0056228)).

Regarding claim 1, Goodman discloses an apparatus (element 10) comprising a pulse wave detection device (element 12); a device for processing the detected pulse wave (element 14); a device for measuring blood pressure (column 13, lines 20-24); and a display unit (element 7). The pulse wave processing device is used to determine characteristic points of the detected pulse wave, calculate characteristic parameters, and calculate an index of a pulse wave reflection from said parameters (column 17, lines 5-11; column 31, lines 12-22). The display unit may be used to show (figure 19) the calculated index on one axis of a 2-D graph (element 504) and the measured blood pressure on a second axis (element 500). The apparatus also comprises a communication network (element 18) that is used to bring the local results into contact with outside storage, databases, and users, so that further processing and analysis of the patient's condition may be assessed.

Utsugi teaches a communication network for health systems that is used to bring local results into contact with outside storage, databases, and users (Figures 1, 3, and 4). The communication network is also used to allow a prescription data processing section to communicate with the subject, so that prescriptions may be displayed in response to the subject's physiological measurements in order to reduce the amount of time between testing and diagnosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Goodman with the prescription data processing section of Utsugi as part of the communication network in order allow prescriptions to be determined and rapidly displayed to a user.

Regarding Claim 3, Goodman'613 further discloses that said index may be a measure of time between a component of the traveling wave and component of the reflected wave (column 24, lines 48-51).

Regarding claim 12, Goodman discloses an apparatus (element 10) comprising a pulse wave detection device (element 12); a device for processing the detected pulse wave (element 14); and a display unit (element 7). The processing device may be used to calculate several different indices from the pulse wave (column 23, line 63 to column 24, line 2; and column 24, lines 40-45). The display device may be used to display the correlation between said indices on a 2-dimensional graph (Figure 19). The system also comprises a communication network (element 18) that is used to bring the local results into contact with outside storage, databases, and users, so that further processing and analysis of the patient's condition may be assessed.

Utsugi teaches a communication network for health systems that is used to bring local results into contact with outside storage, databases, and users (Figures 1, 3, and 4). The communication network is also used to allow a prescription data processing section to communicate with the subject, so that prescriptions may be displayed in response to the subject's physiological measurements in order to reduce the amount of time between testing and diagnosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Goodman with the prescription data processing section of Utsugi as part of the communication network in order to reduce the amount of time between testing and diagnosis.

Regarding Claim 14, Goodman further discloses that said apparatus may be used to measure blood pressure (column 13, lines 20-24), and that the blood pressure measurement may be displayed on the display, as shown in Figure 19 (column 26, lines 3-6; column 35, lines 36-39).

3. Claims 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Utsugi, as applied to claims 1, 3, 12, and 14 above, and further in view of Ogura (US Patent Application Publication 2003/0139675).

Goodman in view of Utsugi discloses all the elements of the current invention, as described above, except for the first characteristic point of the characteristic points corresponding to a peak of a traveling wave component of the detected pulse wave and a second point corresponding to a peak of a reflection wave component of the detected

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pulse wave, where the index is a ratio of amplitudes of the pulse wave at the first and second characteristic points.

Ogura teaches a device comprising a pressure pulse wave detection device (element 36); a device for processing the detected pressure pulse wave (element 32); a device for measuring blood pressure (element 86); and a display unit (element 79). The pulse wave processing device is used to determine characteristic points of the detected pulse wave, calculate characteristic parameters, and calculate an index of a pulse wave reflection from said parameters (paragraph [0050]). The display unit is used to display the calculated index and measured blood pressure (paragraph [0054]). The characteristic points used to determine the index are peak points of the traveling and reflected pressure pulse waves, and that the index is a ratio of the amplitude of the wave components at those peak points (paragraph [0050]), since this ratio is well-known in the art to be a good indicator of a patient's health status. It would have been well-known in the art at the time the invention was made to have made the apparatus of Goodman in view of Utsugi and used the ratio of peak points of the forward and reflected pulse wave components as the index, as taught by Ogura, since this ratio is well-known in the art to be a good indicator of a patient's health status.

Regarding claim 5, Ogura further teaches that the index comprises an augmentation index (paragraph [0002]), since this type of index is commonly used to measure a patient's health status. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Goodman in

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view of Utsugi and Ogura and found an augmentation index, as taught by Ogura, since this type of index is commonly used to measure a patient's health status.

Regarding claim 6, Ogura further teaches that the index is determined as function of the pulse of the subject (paragraph [0065]), since this is well-known in the art as an accurate basis for an augmentation index. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Goodman in view of Utsugi and Ogura and determined the index as a function of the subject's pulse, as taught by Ogura, since this is well known in the art as an accurate basis for an augmentation index.

4. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Utsugi, as applied to claims 1, 3, 12, and 14 above, and further in view of Hatschek (US Patent 5309916).

Regarding Claim 7, Goodman in view of Utsugi discloses all the elements of the current invention, as applied to Claim 3 above, except for the index comprising the time difference between the starting point of an ejection wave and the starting point of a reflection wave ( $\Delta T_P$ ).

Hatschek teaches measuring the difference in phase between an ejection wave and a reflected wave (column 7, lines 51-56) in order to measure the velocity of the pressure pulse wave (column 8, lines 16-20) so that a more clear status of the patient's condition may be determined. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the apparatus of Goodman in

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view of Utsugi with the index comprising the time difference between the starting points of the ejection and reflection waves, as taught by Hatscek, in order to more clearly determine the status of the patient's condition.

Regarding Claim 8, Goodman further discloses that the pulse wave velocity may be adjusted for the height of the patient (column 23, lines 13-15; column 24, lines 56-58).

5. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Utsugi, as applied to claims 1, 3, 12, and 14 above, and further in view of Tanaka (US Patent Application Publication 2004/0077960).

Regarding claim 16, Goodman in view of Utsugi discloses all the elements of the current invention, as described above, and further discloses that the device comprises a central processing unit (CPU) (element 5) that is used to store the physiological data to memory for future retrieval (column 18, lines 14-16). Goodman does not disclose the memory unit storing the data in chronological order.

Tanaka teaches a device for measurement of physiological signals comprising a memory device that stores said signals in chronological order (paragraph [0035]), in order to more easily store and retrieve the data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the device of Goodman in view of Utsugi with the chronological memory storage of Tanaka, in order to more easily store and retrieve the data.



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Regarding claim 18, Goodman further discloses the display unit (element 7) may be used to display data stored in the CPU (element 5) (column 18, lines 16-17).

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1-3, 5-8, 12, 14, 16, and 18 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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